L6: Entry 10 of 14 File: USPT Sep 15, 1998

US-PAT-NO: 5807579
DOCUMENT-IDENTIFIER: US 5807579 A

TITLE: Pseudoephedrine combination pharmaceutical compositions

DATE-ISSUED: September 15, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
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US-CL-CURRENT: 424/469; 424/481, 424/482

CLAIMS:

We claim:

1. A pharmaceutical tablet composition for oral administration comprising:

(a) a plurality of pellets, each pellet being about 300 to 1500 microns in size and having a core of pseudoephedrine, or a pharmaceutically acceptable salt thereof, in an amount from about 30% to about 80% by weight of the core, in association with a binder in an amount from about 30% to about 50% by weight of the core, and a coating surrounding the core, wherein the coating comprises a water-soluble polymer and a water-insoluble polymer, the ratio of the water-soluble polymer to the water-insoluble polymer being effective to provide an extended release of pseudoephedrine; and

(b) a tablet mixture containing (i) a therapeutically effective amount of an active drug other than pseudoephedrine, including any pharmaceutically acceptable salt thereof, (ii) sodium bicarbonate in an amount from about 1% to about 15% by weight of the mixture, (iii) a powdered cellulose in an amount from about 10% to about 50% by weight of the mixture, (iv) optionally one or more inert ingredients, but not any

anionic or nonionic surfactants, and (v) optionally a therapeutically effective amount of pseudoephedrine, or a pharmaceutically acceptable salt thereof, wherein the tablet mixture provides an immediate release of the active drug and of any pseudoephedrine, said tablet mixture having dispersed therein said plurality of pellets.

2. The tablet composition of claim 1, wherein the binder in the pellet core is microcrystalline cellulose or cornstarch.

3. The tablet composition of claim 1, wherein the active drug is an antihistamine.

4. The tablet composition of claim 3, wherein the antihistamine is selected from the group consisting of azatadine, loratadine, terfenadine, astemizole, chlorpheniramine, brompheniramine, acrivastine, hydroxyzine, pheniramine, diphenhydramine, mebhydroline, cyproheptadine, promethazine, dexchloropheniramine, cetirizine, triprolidine, and pharmaceutically acceptable salts thereof.

5. The tablet composition of claim 1, wherein the water-soluble polymer is selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol having a molecular weight of from 1700 to 20,000, and mixtures thereof.

6. The tablet composition of claim 1, wherein the water-insoluble polymer is selected from the group consisting of ethylcellulose, cellulose acetate phthlate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, methacrylic acid copolymer, hydroxypropyl methylcellulose acetate succinate, shellac, cellulose acetate trimellitate, and mixtures thereof.

7. The tablet composition of claim 1, wherein the polymer coating further comprises a plasticizer and a lubricant.

8. A pharmaceutical tablet composition for oral administration comprising:

(a) a plurality of pellets, each pellet being about 300

to 1500 microns in size and having a core of pseudocphedrine, or a pharmaceutically acceptable salt thereof, in an amount from about 30% to about 80% by weight of the core, in association with a binder in an amount from about 30% to about 50% by weight of the core, and a coating surrounding the core, wherein the coating comprises a water-soluble polymer and a water-insoluble polymer, the ratio of the water-soluble polymer to the water-insoluble polymer being effective to provide an extended release of pseudoephedrine;

(b) a tablet mixture containing (i) sodium bicarbonate in an amount from about 1% to about 15% by weight of the mixture, (ii) a powdered cellulose in an amount from about 10% to about 50% by weight of the mixture, and (iii) optionally one or more inert ingredients, but not any anionic or nonionic surfactants, said tablet mixture having dispersed therein said plurality of pellets;

said pharmaceutial tablet composition further comprising

(c) an outer coating applied to said tablet mixture, said outer coating comprising (i) a therapeutically effective amount of an active drug other than pseudoephedrine, including any pharmaceutically acceptable salt thereof, (ii) one or more inert ingredients, but not any anionic or nonionic surfactants and (iii) optionally a therapeutically effective amount of pseudoephedrine, or a pharmaceutically acceptable salt thereof, wherein the outer coating provides an immediate release of the active drug and of any pseudoephedrine.

9. The tablet composition of claim 8, wherein the binder in the pellet core is microcrystalline cellulose or cornstarch.

10. The tablet composition of claim 8, wherein the active drug is an antihistamine.

11. The tablet composition of claim 10, wherein the antihistamine is selected from the group consisting of azatadine, loratadine, terfenadine, astemizole, chlorpheniramine, brompheniramine and acrivastine, hydroxyzine, pheniramine, diphenhydramine, mebhydroline, cyproheptadine, promethazine, dexchloropheniramine, cetirizine, triprolidine, and pharmaceutically acceptable

salts thereof.

12. The tablet composition of claim 8, wherein the water-soluble polymer is selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol having a molecular weight of from 1700 to 20,000, and mixtures thereof.

13. The tablet composition of claim 8, wherein the water-insoluble polymer is selected from the group consisting of ethylcellulose, cellulose acetate phthlate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, methacrylic acid copolymer, hydroxypropyl methylcellulose acetate succinate, shellac, cellulose acetate trimellitate, and mixtures thereof.

14. The tablet composition of claim 8, wherein the polymer coating further comprises a plasticizer and a lubricant.

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Quinn; Eugene	Prospect			AU

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FIELD-OF-SEARCH: 424/464, 424/469, 424/481, 424/482

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

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	PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
☐	4975426	December 1990	Sunshine et al.	514/159
☐	4996061	February 1991	Webb et al.	424/475
☐	5032406	July 1991	Dansereau et al.	424/472
☐	5314697	May 1994	Kwan et al.	424/480
☐	5338550	August 1994	Edgren et al.	424/472
☐	5368861	November 1994	Ushimara et al.	424/472

OTHER PUBLICATIONS

Pharmaceutical Technology Europe, Feb. 1994, "Development and Industrial Scale-Up of Tablets Containing Modified-Release Pellets", pp. 19-25.

ART-UNIT: 165

PRIMARY-EXAMINER: Kulkosky; Peter F.

ABSTRACT:

A pharmaceutical tablet composition for oral administration containing pseudoephedrine pellets admixed with a tablet mixture containing a second active drug substance, either alone or in combination with pseudoephedrine or a pharmaceutically acceptable salt thereof, is disclosed. The pellets provide an extended release of pseudoephedrine, whereas the tablet mixture provides an immetliate release of the second active drug and any pseudoephedrine.

14 Claims, 0 Drawing figures